



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Amy Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Middle East Respiratory Syndrome Coronavirus Antibodies

Description of Technology:

Middle East Respiratory Syndrome coronavirus (MERS-CoV) causes a highly lethal pulmonary infection with ~35% mortality. Currently there are no prophylactic measures or effective therapies. Inventors at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases have identified and developed neutralizing monoclonal antibodies (nMAbs) against the MERS-CoV. This invention describes antibodies that target the Spike (S) glycoprotein on the coronavirus surface, which mediates viral entry into host cells. These novel antibodies target different regions of the S protein, and when administered in combination, reduce the possibility of viral escape. In preclinical testing, these nMAbs have demonstrated potent protective effects, preventing death, viral replication in the lower airways and severe disease in challenge studies with mice. In addition, these nMAbs have potential application for use in assays for detecting MERS-CoV S protein in infected patients or animals.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

Monoclonal antibodies developed against multiple regions of the coronavirus spike protein have potential application in the prevention and treatment of MERS-CoV. There is also potential application for their use as a diagnostic tool of infection.

Competitive Advantages:

- *In vitro* models, the combinations of antibodies have been demonstrated to be effective in reducing viral escape.
- *In vivo* data in animal models demonstrated a potent ability to control infection.
- Applicable in diagnostic assays

Development Stage:

- *In vivo* data available (animal)

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Intellectual Property: HHS Reference No. E-239-2014, U.S. Provisional Patent Application Number 62/120,353 filed February 25, 2015, PCT Patent Application PCT/US2016/019395 filed February 24, 2016, Europe Patent Application Number 16711059.2 filed February 24, 2016, South Korea Patent Application Number 10-2017-7027105 filed September 25, 2017, Saudi Arabia Patent Application Number 5173382168 filed August 21, 2017, and U.S. Patent Application Number 15/553,466 filed August 24, 2017.

Licensing Contact: Amy Petrik Ph.D., 240-627-3721; amy.petrik@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize MERS-CoV

monoclonal antibodies. For collaboration opportunities, please contact Amy Petrik,
Ph.D., 240-627-3721; amy.petrik@nih.gov.

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Suzanne M. Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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